Scientific Research Publishing

Open Journal of Nephrology, 2020, 10, 158-169
https://www.scirp.org/journal/ojneph
ISSN Online: 2164-2869
ISSN Print: 2164-2842

Portable Hemodialysis Machine for Chronic Hemodialysis in Hospital—Advantages and Future Uses

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How to cite this paper: Alhazmi, A.I., Mohsin, B. and Khamis, S.S.A. (2020) Portable Hemodialysis Machine for Chronic Hemodialysis in Hospital—Advantages and Future Uses. *Open Journal of Nephrology*, **10**, 158-169.
https://doi.org/10.4236/ojneph.2020.102016

Received: May 17, 2020
Accepted: June 27, 2020
Published: June 30, 2020

Abstract

Introduction: Nx stage one machine results can help to enhance the clinical efficiency and shortage concerning the use of home hemodialysis. Therefore, the study investigates effectiveness of Nx stage machine for intermittent conventional hemodialysis in hospital for inpatients and outpatients to replace conventional hemodialysis in stable chronic hemodialysis patients. **Methods:** Prospective observatory study was conducted in Nephrology Division, King Fahd General Hospital from April 1 to June 1 2018. Patients with ESRD, who were dependent on dialysis and maintained on regular hemodialysis were recruited. Fifty-two sessions of hemodialysis were performed. The patients were given intermittent dialysis using Nx stage one machine. Pre and Post dialysis investigations and body weight were taken, and patients were observed for any complications during or post-dialysis. **Findings:** The primary endpoint ultrafiltration with a goal to remove 1 - 4 kg was achieved without any technical difficulty. Secondary endpoint for potassium reduction levels was achieved with mean SD post-dialysis 3.53 ± 0.3, and the tertiary endpoint was achieved in a patient less than 50 kg weight with spKt/V above 1.2. It was difficult to achieve spKt/V in patients with weight more than 60 kg due to limitations in the duration of sessions or dialysate volume. Target spkT/V was achieved for patients with body weight less than 50 kg; however, it was not achieved among the patients with body weight more than 60 kg. **Discussion:** Nx stage one machine can replace conventional intermittent dialysis in terms of ultrafiltration and Potassium correction; however, further investigation is needed for urea clearance.

Keywords

Body Weight, Hemodialysis, Nx Stage One S, Nx Stage One, SPKT/V, Urea Reduction Ratio (URR)

1. Introduction

Incidence and prevalence of chronic diseases, such as chronic kidney disease (CKD) have increased due to progressive aging population [1]. End-stage kidney disease (ESRD) is a leading cause of morbidity and mortality affecting more than 1,000,000 individuals worldwide. A study reports more than 1.2 million premature deaths in 2010 due to untreated ESRD related to diabetes and hypertension [2]. Prevalence of the disease and worldwide use of renal replacement therapy (RRT) are expected to rise sharply in the next decade [3], driven by increasing prevalence of diabetes and hypertension [4] [5] [6]. The number of people receiving RRT is likely to rise and double from 2.618 million in 2010 to 5.439 million (95% CI 3.899 - 7.640 million) in 2030, based on demographic projections and expected rates of economic growth [7].

Chronic hemodialysis remains the mainstay of treatment; while, renal transplantation offers a durable treatment for ESRD [8]. More options are available for renal replacement therapies with a growing interest in frequent hemodialysis [9]. Such as Nx stage system, which is a portable machine used for home hemodialysis with easy access, fast learning [10], and easy portability [11]. It does not require infrastructure modification for water purification, electricity delivery, and specialized disinfection or plumbing [12] [13]. It is a flexible device that delivers hemodialysis, hemofiltration, and/or ultrafiltration therapies to patients with renal failure or fluid overload [14]. It allows the use of high-quality premixed treatment fluids to enable capture of the potential clinical benefits of fluid purity without the hassles of local water treatment. Moreover, the wide operating ranges allow clinician flexibility inpatient therapy prescriptions [15]. The dialysate is supplied at very low flux, usually about one-third of blood flow rate to achieve elevated saturation of dialysate for solutes [8].

The need to assess the impact of the Nx stage machine as a dialysis tool stems from the increased rate of ESRD across the world [3]. The use of home hemodialysis is low; although, the advantage of home hemodialysis over conventional dialysis in terms of cost and improved quality of life is established [16]. US renal disease Data System shows that only 1.8% are using home hemodialysis; whereas, the major portion (84.5%) is still dependent on the in-center dialysis across 42 countries [17].

The use of Nx stage and its effectiveness enhance the treatment options for the ESRD patients. Its use is affected by equipment size, challenges in its deployment, its usage literacy [18] [19]. It offers water purification and dialysate production in one integrated unit specifically designed for use at home or in-center hemodialysis. The number of ESRD patients increases due to the longer life span [20] [21]. It has several similarities to conventional HD machine, such as: blood flow rate modification, monitoring blood and fluid circuit pressures, working with any vascular access (graft, fistula, catheter), and use of anticoagulation [22]. Inadequate removal of small and medium molecules along with resultant high blood levels and elevated total body burden is associated with long term morbid-

ity and mortality. However, data on the clearance of solute other than urea in patients dialyzing with low dialysate flow approach is limited [8].

The present study aims to test using Nx Stage PureFlow SL machine for intermittent conventional hemodialysis in hospital for inpatients and outpatients to replace for conventional hemodialysis in stable chronic hemodialysis patients. Investigating the Nx stage one machine results can help to enhance the clinical efficiency and shortage concerning the use of home hemodialysis. The ability of the machine to make ultrafiltration and solute clearance of small and medium molecules, including urea, potassium, phosphorous was assessed during the trial. The dialysis adequacy by calculating the urea reduction ratio and Single pool KT/V was also assessed. Moreover, the machine was assessed for the possibility of blood transfusion during dialysis and observed for any complications related to the machine or adverse events in association with the patients.

2. Material and Methods

The study has employed prospective observatory design that was performed in Dialysis facility of King Fahd General Hospital, Jeddah. The duration of this study was eight weeks from 1st April 2018 to 1st June 2018. Patients from both the genders, using hemodialysis as a modality of Renal Replacement therapy were included in the study. The age of the patients was between 24 and 67 years. The pre-Dialysis bodyweight of the patient varied from 44 kg to 83 kg.

The inclusion criteria for this study were patients suffering from hypertension, had no residual renal function, were anuric, and were depended on dialysis since 1 to 7 years. The patients with any malignancy, viral hepatitis, or pregnancy were excluded from the study design. The patient included in the study had Working AVF or tunneled HD catheter. Around 52 distinct sessions of HD were included in this study, after the exclusion of the patients who did not meet the inclusion criteria. Informed consent was taken from the patients at the start of hemodialysis process.

Nx stage one machine was used to give intermittent dialysis to these patients. The maximum dialysate volume available per hour with this machine was 12 L/hr. Duration of sessions was 3 hours in 15 sessions and 4 hours in 37 sessions. The blood flow rate was 350 to 500 ml/min. The volume of Dialysate per session varied from 30 L to 50 L; for instance, 30 L in 19 sessions, 40 L in 13 sessions, and 50 L in 20 sessions. Fifty-two sessions of dialysis were done using Nx stage one machine. Pre HD and Post HD bodyweight and investigations were taken, including serum BUN, K, Ca, and PO4. Blood samples were taken by nurses and helpers following the KDOQI guidelines [23]. Post dialysis samples were taken via the two-needle technique using the slow blood flow method. SPKT/V and Urea Reduction Ratio (URR) were calculated. Eight sessions were discarded due to incomplete data. An electronic database and paper-based patient records were used to select the study population and compile a list of demographic details and clinical information. A data sheet was used to capture the demographic details,

investigations, spKT/V, and URR.

In the present study, Urea Reduction Ratio (URR) refers to the treatment-related reduction of serum urea concentration and is computed [24] as follows;

$$\mathrm{URR} = \left(\mathrm{Upre} - \mathrm{Upost}\right)/\mathrm{Upre} \times 100 = \left(1 - \mathrm{Upre}/\mathrm{Upost}\right) \times 100$$

where;

Upre = urea pre-dialysis.

Upost = urea post dialysis.

Single pool Kt/V is based on URR and accounts for intradialytic urea generation and ultrafiltration volume. The ultrafiltration was targeted per treatment. The Daugirdas equation [25] is as follows;

$$\mathrm{SpKT/V} = -\ln\left(\left(\mathrm{BUNPost}/\mathrm{BUNPre}\right) - \left(0.008 \times \mathrm{Hours}\right)\right) + \left(\left(4 - \left(3.5 \times \mathrm{BUNPost}/\mathrm{BUNPre}\right)\right) \times \mathrm{UFVol}/\mathrm{WeightPost}\right).$$

where:

In = natural logarithm.

t = treatment time in hours

UF = ultrafiltration volume in Liters and patients post dialysis body weight in kilograms [25] [26].

Descriptive statistical analysis was performed using SPSS version 22. Frequency and percentages were computed to present categorical variables such as Pre HD, Post HD K, PO_4, and body weight. All continuous response variables such as URR, spKT/V, and biochemical parameters were presented as the mean ± SD. Statistical significance was considered at $P \leq 0.05$.

3. Results

The demographic analysis patients revealed that majority of them were male with the mean age of 48.3 (±12.8). Whereas, the mean BMI of the patients is found to be 27.7 (±6.1) (**Table 1**).

3.1. Ultrafiltration

Machine work well to achieve the primary endpoint with fluid removal range from 1 - 4 L per session, without complication other than usual like hypotension

Table 1. Participants demographics.

Variables	Inpatients	Outpatients
Gender		
Male	17 (68%)	32 (74.4%)
Female	8 (32%)	11 (25.5%)
Age	51.8 (±14.1)	46 (±13.2)
Body mass index (kg/m^2)	25 (±5.2)	27.8 (±6.6)

and cramps during the session if more than 2 L of the volume is removed in few patients. All outpatients received 4 hours dialysis with dialysate volume of 46.06 ± 4.96 liters. The mean patients weight decreases from a mean of 62.38 ± 11.7 kg to 60.5 ± 12.18 kg (a mean weight reduction of 1.88 kg which is clinically significant) with mean UF 2.51 ± 0.86 (Figure 1). Inpatients received 3 - 4 h sessions, which removed 1 - 2.5 L of fluid in all patients without any unusual complication.

3.2. Electrolyte Imbalance

There was a significant response for potassium and phosphorus reduction with maintained calcium level, where the secondary endpoint was achieved for both group's inpatients and outpatients using different dialysate volume *i.e.*, 30 L, 40 L, or 50 L. For outpatients, potassium means SD pre-dialysis was 5.64 ± 0.95 and mean SD for post-dialysis was 3.53 ± 0.3 ($p < 0.001$). Moreover, for phosphorus, mean SD pre-dialysis was 6.55 ± 1.36 and mean SD for post-dialysis 3.38±0.63 ($p < 0.001$) (Table 2 and Figure 2). For inpatients, potassium mean SD pre-dialysis was 4.78 ± 1.06 and mean SD for post dialysis was 3.46 ± 3.98 ($p < 0.001$). Moreover, for inpatients, phosphorus mean SD pre-dialysis was 4.62 ± 1.9 and mean SD for post dialysis was 3.04 ± 1.16 ($p < 0.001$) (Table 3 and Figure 2). A K-path used was 2 and 3 based on potassium level.

For inpatients, the target urea clearance was not achieved based on urea reduction ratio because dialysate volume of 30 L was used (Figure 3), and spKt/V was difficult to calculate because bodyweight was difficult to obtain. For inpatient group URR had a mean value of 45.25 ± 13.63. For outpatient's duration of

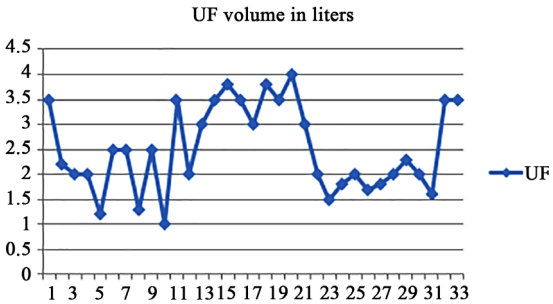

Figure 1. UF volume in outpatients.

Table 2. Changes in serum electrolytes in outpatient group.

	Pre-Dialysis (Mean ± SD)	Post Dialysis (Mean ± SD)	P-Value
Serum CR (mg/dl)	14.79 ± 2.62	6.06 ± 1.01	<0.001*
Serum K (mg/dl)	5.64 ± 0.95	3.53 ± 0.3	<0.001*
Serum P (mg/dl)	6.55 ± 1.36	3.38 ± 0.63	<0.001*
Serum Urea (mg/dl)	69.45 ± 15.66	27.33 ± 6.39	<0.001*
Serum CA (mg/dl)	8.83 ± 1.31	9.32 ± 0.55	0.06

CR = Creatinine, K = Potassium, P = Phosphorus, CA = Calcium, * is Significant.

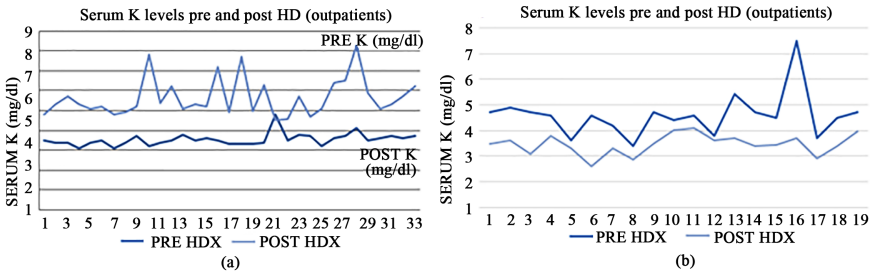

Figure 2. Changes in serum K level in (a) Outpatient group; (b) Inpatient group.

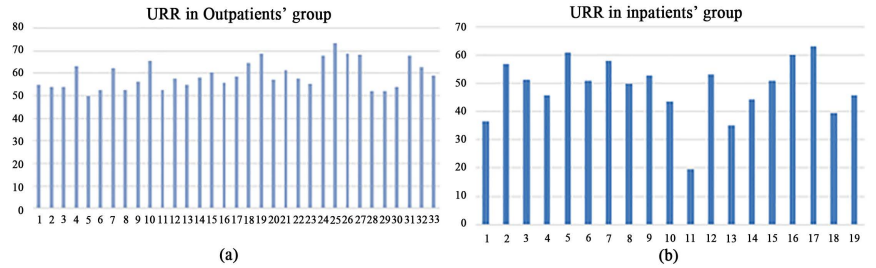

Figure 3. Urea reduction ratio in (a) Outpatient group; (b) Inpatient group.

Table 3. Changes in serum electrolytes in inpatient group.

	Pre-Dialysis (Mean ± SD)	Post Dialysis (Mean ± SD)	P-Value
Serum CR (mg/dl)	13.82 ± 5.46	5.58 ± 3.13	<0.001*
Serum K (mg/dl)	4.78 ± 1.06	3.46 ± 3.98	<0.001*
Serum P (mg/dl)	4.62 ± 1.9	3.04 ± 1.16	<0.001*
Serum Urea (mg/dl)	60.52 ± 21.51	32.07 ± 11.3	<0.001*
Serum CA (mg/dl)	8.03 ± 1.22	8.96 ± 0.91	0.07

CR = Creatinine, K = Potassium, P = Phosphorus, CA = Calcium, * is Significant.

each session was 4 hours. Dialysate volume was 40 L in 15 sessions and 50 L in 18 sessions. The mean value of URR was 58.5 ± 6.06. Patients were stratified with body weight less than 50 kg, 50 - 70 kg, and more than 70 kg. The SPKT/V was calculated using Daugradaus formula. Five sessions with body weight less than 50 kg achieved SPKT/V more than 1.2 with both dialysate volumes 40 L and 50 L (**Figure 4**). Nine sessions were observed for patients with body weight 51 kg to 70 kg with volume of dialysate 50 L and SPKT/V varied between 0.97 and 1.39. Four patients achieved SPKT/V more than or equal to 1.2 (**Figure 4**). 6 sessions were observed for patients with body weight 51 - 70 kg with dialysate volume 40 L. SPKT/V varied between 1 and 1.11 as shown in (**Figure 4**). Five sessions were observed for body weight more than 70 kg and volume of dialysate 40 L. In all sessions SPKT/V was less than 1.0 with values varying between 0.83 and 0.94 (**Figure 4**). Moreover, 8 sessions were observed for body weight more than 70 kg and volume of dialysate 50 L. However, SPKT/V varied between 0.86 and 1.13 (**Figure 4**).

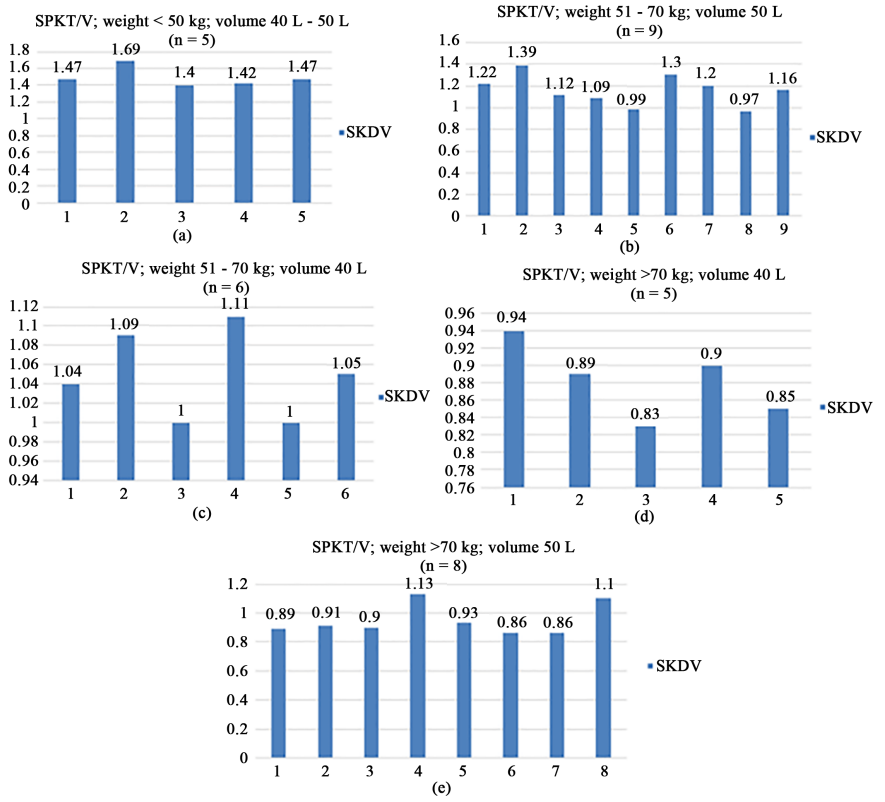

Figure 4. Spkt/V in Patients with Bodyweight (a) below 50 Kg in Outpatient Group; (b) between 51 - 70 Kg in Outpatient Group; (c) between 51 - 70 Kg in Outpatient Group; (d) above 70 Kg in Outpatient Group; (e) above 70 Kg in Outpatient Group.

4. Discussion

The assessment of Nx stage machine in the present study revealed that it can be used as a replacement for conventional hemodialysis machine to provide intermittent hemodialysis. The apparatus and techniques used in the present study were like the ones used by Kohn *et al.* [12] including the dialysis machine, dialyzer, dialysate fluid composition, dialysate flow rate, sample collection, and duration. There were many similarities in both the studies as the patients in both the studies were oligoanuric and dialysis-dependent. However, there were several differences in the present study, as compared to the study by Kohn *et al.* [12]. The present study stratified dialysate volume in 30 L, 40 L, and 50 L, which was different from the other study in which their dialysate volume was 25 ± 4.7 L. In the present study, the patients were stratified according to body weight in three groups. Moreover, SPKT/V, URR, Potassium and Phosphorous kinetics, ultrafiltration were observed whereas they observed; whereas, Kohn *et al.* [12] observed weekly KT/V, B2 microglobulin levels, and Potassium and Phosphate kinetics.

The present study showed that the machine was successful in achieving ultrafiltration goals equals to 6 days a week that was similar to the results presented by Kohn *et al.* [12]. The volume of ultrafiltration per week was equivalent to Kohn *et al.* [12] with a frequency three times per week as compared to 6 times per week. The same finding was observed in patients with different body weight

and both in inpatients and outpatients. However, hypotension and cramps were encountered in few cases of inpatients group with ultrafiltration target more than 3 kg. It did not need termination of dialysis, and all patients responded to conservative measures and completed their session. The outpatient's group did not encounter any adverse symptoms associated with ultrafiltration. The system worked well regarding solute clearance, including Potassium and Phosphorous. There were significant Potassium and Phosphorous reduction noted in post HD. Moreover, significant clearance was observed in both inpatient and outpatient group in all three bodyweight groups with different volume of dialysate.

Brunati *et al.* [27] showed short, frequent home hemodialysis with Nx Stage System One cycler, on a six days per week-based prescription that allows higher weekly Phosphate removal than standard bicarbonate dialysis. The findings of the present study suggested adequate Phosphate removal with intermittent hemodialysis in all patient groups, even though dialysis was performed three times per week as compared to 6 times per week by them. Another study done by Brahmbhatt *et al.* [28] reported a case of a successful conception and pregnancy using the home NxStage system. They reported ultrafiltration, solute clearance, and HD adequacy with six days a week HD during pregnancy. However, the present study observed adequate ultrafiltration, solute clearance in all the patients in different groups, and achieved spkt/V among patients' weight less than 60 kg with HD frequency three times per week. The findings were comparable to the present study in this regard, but there were a few differences, as none of the patients was pregnant in the present study. The present study used intermittent HD three times per week, and the patient population was stratified in different groups according to HD duration, dialysate volume, and body weight.

The NxStage System may provide an alternative to the more routinely used Nocturnal hemodialysis or standard Short Duration Hemodialysis therapies for women of childbearing age. Brunati *et al.* [28] found that the dialysis sessions are repeated six times a week because the dialysate is supplied at very low flux, generally about 1/3 of blood flow to obtain an elevated saturation of dialysate for solutes to achieve an optimal weekly clearance evaluated by spkt/V. The present study achieved target spkt/V in dialysis patients with frequency three times per week in the patient group less than 60 kg body weight. The unique point of present study is that it used the Nx stage one system three times per week as a replacement to conventional dialysis as compared to short daily dialysis for six days a week, unlike previous studies [12] [27] [28].

Kraus *et al.* [29] demonstrated the safety of center-based vs. home-based daily hemodialysis with the Nx Stage System One portable hemodialysis device. The study results concluded that daily home hemodialysis with a small, easy-to-use hemodialysis device is a viable dialysis option for end-stage renal disease patients. These results were consistent with the results of the present study for using Nx stage system one in- and looking for the safety and efficacy of dialysis. However, there was one difference between both the studies, as the present study had used this device for home hemodialysis sessions for intermittent HD.

Moreover, the patients in the present study were stratified in subgroups according to dialysate volume, duration, body weight, and mode of presentation, which was not done by Kraus *et al.* [29].

Brunelli *et al.* [30] assessed clinical parameters and outcomes in home hemodialysis patients using either Fresenius 2008 K@home or Nx Stage System One over one year. The study concluded that clinical parameters and outcomes for both the systems were largely equivalent. They used Nxstage one as a tool in home hemodialysis with good clearance adequacy and ultrafiltration. The present study used Nx stage one as a tool in intermittent dialysis. The results of the present study were comparable in terms of ultrafiltration and solute clearance in all the patient population, where HD adequacy was acceptable inpatient population less than 60 kg of body weight. These results have clearly shown that this machine works well in ultrafiltration, with electrolyte imbalance like hyperkalemia and hyperphosphatemia. It is portable, which keeps it more convenient to use in any place and is easy to learn. However, one of its weakness is inadequate clearance, especially in patients with bodyweight above 60 kg.

The results of the present study have concluded that Nx Stage one machine could replace conventional hemodialysis machine for stable chronic hemodialysis patients with regards to the management of electrolyte imbalance and volume overload. The use of the Nx One stage machine is observed to overcome the drawbacks associated with conventional HD. The results show that Nx stage one machine can provide adequate hemodialysis with achieving target spkt/v in patients less than 50 kg. However, target spkt/v could not be achieved, especially in patients with body weight more than 60 kg. This can be rectified with more dialysate volume 50 - 60 L, longer sessions, or with dialysis frequency four times per week. However, the results of this study are limited as Nx stage one machine does not allow dialysate volume of more than 50 liters. The duration of dialysis could not be extended to more than 4 hours. These can be the contributing factors for the inability to achieve SPKT/V in patients with body weight more than 60 kg of weight. The study also suggests that the use of Nx Stage one machine as home hemodialysis cannot be ensured given the different barriers. For instance, the need for stable electricity and clean water cannot be available at home. Future studies need to conduct dialysis sessions of longer duration and increased frequency of sessions with the same machine or with Nx stage one machine. This would enable the researcher to use more volume of dialysate per hours i.e., 18 L/hr so that it is possible to assess the adequacy of dialysis, especially in population with bodyweight more than 60 kg.

Acknowledgements

The author is very thankful to all the associated personnel in any reference that contributed in/for the purpose of this research.

Conflicts of Interest

The authors declare no conflict of interest.

Funding

The study is not funded through any source.

Ethics Approval

Ethics approval was obtained from Research and Studies Department Jeddah Health Affairs (KACST, KSA: H-02-J-002). (Review Number A00722).

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